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# TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER 51298-00004 US

J.S. AP 10 TION NO 41 150MP, SEE 37 CFR 1.5)

INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE PRIORITY DATE CLAIMED PCT/US2003/030902 27 September 2002 29 September 2003 TITLE OF INVENTION IMPLANTABLE STENT WITH MODIFIED ENDS APPLICANT(S) FOR DO/EO/US MEDLOGICS DEVICE CORPORATION Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. The US has been elected (Article 31). A copy of the International Application as filed (35 U.S.C. 371(c)(2))

		a. is attached hereto (required only if not communicated by the International Bureau).					
		b.  has been communicated by the International Bureau.					
		c. Is not required, as the application was filed in the United States Receiving Office (RO/US).					
6.		An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).					
		a. is attached hereto.					
		b. has been previously submitted under 35 U.S.C. 154(d)(4).					
7.	$\checkmark$	Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))					
		a. are attached hereto (required only if not communicated by the International Bureau).					
		b. have been communicated by the International Bureau.					
		c. have not been made; however, the time limit for making such amendments has NOT expired.					
		d. An have not been made and will not be made.					
8.		An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).					
9.	Ø	An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).					
10.		An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).					
	Items	ems 11 to 20 below concern document(s) or information included:					
11.	$\checkmark$	An Information Disclosure Statement under 37 CFR 1.97 and 1.98.					
12.		An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.					
13.	=	A preliminary amendment.					
14.	$\overline{\square}$	An Application Data Sheet under 37 CFR 1.76.					
15.		A substitute specification.					
16.	$\Box$	A power of attorney and/or change of address letter.					

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825.

A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

A second copy of the published International Application under 35 U.S.C. 154(d)(4).

Other items or information: Cited references; PTO/SB/08A

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## JC17 Rec'd PCT/PTO 24 MAR 2005

PTO-1390 (Rev. 02-2005)
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U.S. APPLICATION NO (if known see 37 OF 83.5) INTERNATIONAL APPLICATION NO. PCT/2003/030902			ATTORNEY'S DOCKET NUMBER					
1	0/72	7100	PCT/2003/030902		51298-00004 US			
The follow	ving fees have b	peen submitted	•		CALCULATIONS	PTO USE ONLY		
21. 📝 Basic	21.			\$300	<sup>\$</sup> 300.00			
If International pre	1)-(4)	<sup>\$</sup> 100.00						
23. Search Search fee (37 CF International Search All other situations	R 1.445(a)(2)) h al Searching Au th Report prepar	\$ 100.00						
ī	OTAL OF 21, 2	\$ 500.00						
Additional fee sequence list	for specification ng or computer 50 for each addi							
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)		RATE				
95 <sub>- 100</sub> =	0 /50 =	. 0		× \$250	\$ 0.00			
Surcharge of \$130 claimed priority da			laration later than 30 months fi	rom the earliest	\$			
CLAIMS	NUME	BER FILED	NUMBER EXTRA	RATE	\$			
Total claims	23	- 20 =	3	× \$ 50	\$ 150.00			
Independent claim	s 4	- 3 =	1	× \$200	\$ 200.00			
MULTIPLE DEPE	NDENT CLAIM(	S) (if applicable)		+ \$360	\$ 0.00			
			TOTAL OF ABOVE	CALCULATIONS =	\$ 850.00			
Applicant clair	ns small entity s	tatus. See 37 CF	R 1.27. Fees above are reduc	ced by 1/2.				
				SUBTOTAL =	\$ 425.00			
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).								
		NATIONAL FEE =	\$ 425.00					
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property								
			TOTAL F	EES ENCLOSED =	\$ 425.00			
					Amount to be refunded:	\$		
					Amount to be charged:	\$		
a. A check	a. A check in the amount of \$ to cover the above fees is enclosed.							
b. Please charge my Deposit Account No. 50-3207 in the amount of \$ 425.00 to cover the above fees.  A duplicate copy of this sheet is enclosed.								
c. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-3207 A duplicate copy of this sheet is enclosed.								
d. Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.								
NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.								
SEND ALL CORR	SEND ALL CORRESPONDENCE TO:							
Customer Nu	mber: 48,423	() 2	<del>J</del>					
		Slasky						
			•	NAME				
	54,124 REGISTRATION NUMBER							
I				REGISTRATION	ON NUMBER			

**CERTIFICATE OF MAILING** 

I hereby certify that on 3/24/05, this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service as first class mail in accordance with 37 C.F.R. § 1.8(a) with sufficient postage in an envelope addressed to: Mail Stop Petition, Commissioner of Patents and Trademarks, P.O. Box 1450, Alexandria, VA 22313-1450

1 russes 1

Maria Nadal

#### JC17 Rec'd PCT/PTO 24 MAR 2005 10/529108

Applicant: James C. Peacock III et al.

Serial No.: Unassigned

Filed: Unassigned

Title: IMPLANTABLE STENT WITH

MODIFIED ENDS

Art Unit: Unassigned

Atty Docket No.: 51298-00004

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE PETITION TO MAKE SPECIAL FOR APPLICATIONS RELATING TO BIOTECHNOLOGY FILED BY APPLICANTS WHO ARE SMALL ENTITIES UNDER 37 CRF 1.17(H)

Mail Stop Petition Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Applicant hereby petitions to make this application special because a small entity status has been established, and the subject of the patent application is related to biotechnology and is a major asset of the small entity. The development of the technology will be significantly impaired if examination of the patent application is delayed.

The accompanying ☐ affidavit ☒ declaration by the ☐ applicant

applicant's practitioner

explains establishment of small entity and the development of the technology will be significantly impaired if examination of the patent application is delayed.

The Commissioner is authorized to charge \$130 or any fee which may be required in connection with this Petition to deposit account No. 50-3207.

Respectfully submitted,

Dated 3 (24/05

Louis C. Cullman, Reg. No. 39,645

Customer No. 48,423

PRESTON GATES & ELLIS LLP 1900 Main Street, Suite 600 Irvine, California 92614-7319 Telephone: (949) 253-0900

Facsimile: (949) 253-0902

### 10/529108 JC17 Rec'd PCT/PTO 24 MAR 2005

**PATENT** 

CERTIFICATE OF MAILING

I hereby certify that on 3/2 1/105, this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service as Express Mail in accordance with 37 C.F.R. § 1.8(a) with sufficient postage in an envelope addressed to: Mail Stop Petition, Commissioner of Patents and Trademarks, P.O. Box 1450, Alexandria, VA 22313-1450

Maa ·

Maria Nadal

Applicant: James C. Peacock III et al.

Serial No.: Unassigned Filed: Unassigned

Title: IMPLANTABLE STENT WITH

MODIFIED ENDS

Art Unit: Unassigned

Atty Docket No.: 51298-00004

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

DECLARATION OF LOUIS C. CULLMAN
REGARDING PETITION TO MAKE SPECIAL FOR APPLICATIONS RELATING TO BIOTECHNOLOGY
FILED BY APPLICANTS WHO ARE SMALL ENTITIES UNDER 37 CFR 1.17(H)

Mail Stop Petition Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

- 1. I, Louis C. Cullman, am an intellectual property attorney with the firm of Preston Gates & Ellis LLP. I have been Medlogics Device Corporation's attorney since January 1, 2003.
- 2. The Applicant respectfully requests that this Petition to Make Special be granted based on the significant improvement in patient therapy that will result from the biologically active agent-eluting medical devices disclosed in this invention's compositions and associated methods. Examples of biologically active agents include cytostatic compounds, cytotoxic compounds and nucleic acids.
- 3. The present application specifically pertains to the site-specific delivery of biologically active agents from medical devices including the delivery of biologically active agents to blood vessel walls from medical devices, particularly cardiac stents. Biologically active agent-eluting cardiac stents are expected to significantly improve the standard of care and treatment of coronary artery disease and aneurysms. The

Application No. 10/196,296

Filed: 07/15/2002

Applicant: Michael E. Gertner et al.

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biologically active agent technology being developed by Medlogics Device Corporation to deliver these biologically active agents are applicable to a wide range of medical devices.

- 4. The inventors of the present methods and compositions for creating novel biologically active agent-eluting medical devices have made significant advances in the development of this technology. Those skilled in the art will appreciate that the ability to release biologically active agents locally from medical devices is a significant improvement in the art and will provide improved therapeutics for treatment of human disease.
- 5. The invention disclosed in the present patent application is a major asset of Medlogics Device Corporation.
- 6. As a small entity biotechnology company, Medlogics Device Corporation receives its research funding from private individuals and venture capital funds. The firm's intellectual property is the key asset on which this funding depends and therefore the firm's continued research funding for this important invention is dependent on the timely issuance of a United States Patent on the invention.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-identified patent.

Dated: 3/24/05

Louis C. Cullman

Registration Number 39,645

# Certificate of Express Mail under 37 CFR 1.10 EV 276062748 US<sub>JC17 Rec'd PCT/PTO 24 MAR 2005</sub>

	JUIT REC'T PUTPTU 24 WAR							
I hereby certify that this correspondence is being Express Mail to the United State4s Patent and Trademark Office								
On <u>3/24/05</u> Date								
Muchelle Mass								
Michelle S. Glasky								
Type or printed name of person signing Certificate								
St. 124	949-253-0900							
Registration Number, if applicable	Telephone Number							
Papers Sumitted: 1. Transmittal Letter to US Designated C2. ADS (3 pgs) 3. Declaration (2 pgs) 4. POA (1 pg) 5. Pre. Amend. (11 pgs) 6. Petition to Make Special (1 pg) 7. Dec. of Louis Cullman (2 pgs) 8. PTO/SB/08A 9. IDS (2 PGS) 10. Cited references 11. Postage paid pc.	Office (2 pgs)							